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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,355	11/10/2006	Gerhard Saalmann	274635US23PCT	2809

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
05/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/542,355	SAALMANN ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/17/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election Restriction

Applicant's election with traverse of Group II, claims 23-30 in the reply filed on 02/25/2010 is acknowledged. The traversal is on the ground(s) that examining a composition suitable for the treatment of psoriasis and inflammatory processes of the skin and/or joints of mammals and humans does not present the examiner with a search burden. This is not found persuasive because searching all of the claims would require searching in numerous different classes and subclasses, as well as a different searching focus depending on whether the product or processes are being searched. Thus, the search would pose an undue burden on the Office.

The requirement is still deemed proper and is therefore made **FINAL.**

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 11/17/2005 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voet (US 2003/0176411) in view of Bar-Shalom (US 4,665,063).

Applicant claims are drawn to a pharmaceutical composition comprising a substance of the porphyrin synthesis is 5-aminolevulinic acid, or esters or salts, in combination with a salicylate and an antioxidant such as ascorbic acid.

Voet teaches a composition comprising photodynamic therapeutic agent including 5-aminolevulinic acids (PDT) or esters or pharmaceutically acceptable salts thereof (0081-0082). The composition includes antioxidants such as ascorbic acid (about 0.05% to about 5%) and excipients (0101). Additional disclosure includes that the PDT agents has been used to treat various cancerous lesions, and superficial skin lesions such as actinic keratoses and psoriasis (0006).

Voet fails to teach salicylate such as acetylsalicylic acid in the composition.

Bar-shalom teaches a composition for topical administration in the treatment of various dermatological disorders, e.g. psoriasis comprising acetyl salicylic acid in concentration of about 11-13% (abstract and col. 2 lines 15-21). Additional disclosure includes that acetyl salicylic acid has been well known as a therapeutically active

compound, very effective analgesic, antipyretic and anti-inflammatory agent (col. 1 line 21-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate acetyl salicylic acid into Voet's composition. The person of ordinary skill in the art would have been motivated to make those modifications because Bar-Shalom teaches that acetyl salicylic acid is well know therapeutic agent having effective analgesic, antipyretic and anti-inflammatory activity and reasonably expected success because salicylic acid derivatives (acetyl salicylic acid) is a keratolytic agent, is extensively used as a desquamating agent, exfoliates skin and leads to the extrusion of primary skin lesions.

The amount of 5-aminolevulinic acid; acetylsalicylic acid; and ascorbic acid concentration in a pharmaceutical composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amounts of 5-aminolevulinic acid; acetylsalicylic acid; and ascorbic acid active ingredient in order to achieve the desired results, such as a composition comprising photodynamic therapeutic agent used to treat superficial skin lesions such as psoriasis and inflammatory processes of the skin. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of 5-aminolevulinic acid; acetylsalicylic acid; and ascorbic acid

concentration would have been obvious at the time of Applicant's invention. See In re Boesch, 205 USPQ 215 (CCPA 1980).

Claims 23-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin et al (US 5,145,686) in view of McMillan (US 2004/0048842).

Applicant claims are drawn to a pharmaceutical composition comprising a substance of the porphyrin synthesis is 5-aminolevulinic acid, or esters or salts, in combination with a salicylate and an antioxidant such as ascorbic acid.

Horrobin teaches a topical pharmaceutical composition comprising physiologically acceptable lithium salt together with substances capable of inhibiting the cyclo-oxygenase enzyme, acetylsalicylic acid (abstract and col. 3 lines 50-51) and antioxidant such as ascorbic acid in an amount of from 0.01 to 20 % by weight (col. 2 lines 62+). The composition may be used for the treatment of disorders of the skin such as eczema and psoriasis (col. 4 lines 17-20).

Horrobin fails to teach porphyrin synthesis, 5-aminolevulinic acid in the composition.

McMillan teaches a composition comprising 5-aminolevulinic acid from about 1% to about 40% in a suitable pharmaceutical acceptable carrier or excipient (0046). The composition is effective for treating certain skin disorders including psoriasis (abstract). Additional disclosure includes that the 5-aminolevulinic acid is an effective inducer of protoporphyrin IX when given orally, topically, or by injection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate 5-aminolevulinic acid into Horrobin's composition. The person of ordinary skill in the art would have been motivated to make those modifications because McMillan teaches that 5-aminolevulinic acid is an effective inducer of protoporphyrin IX, a naturally occurring photosensitizer useful in photodynamic therapy (for treating skin disorders such as psoriasis) and reasonably expected success because both Horrobin and McMillan teaches a pharmaceutical composition that can be used in the same field of endeavor, such as for treating certain skin disorders including eczema and psoriasis.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr